510(k) Summary 240 Parus Pie Medical

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR \$807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent

8000 Castleway Drive Indianapolis, IN 46250

Phone:

(317) 849-1916

Facsimile:

(317) 5779070

Contact Person:

Colleen Hittle

Date:

November 27, 2000

807.92(a)(2)

Trade Name:

240 Parus Ultrasound Imaging Systems

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulsed echo imaging system

892.1560

Classification Number:

90IYO

807.92(a)(3)

Predicate Device(s)

Pie Medical

250

K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary 240 Parus Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 240 Parus ultrasound systems used are to perform general diagnostic ultrasound studies under a physician's supervision including: abdominal, small organ, fetal, pediatric, peripheral vascular, intraoperative abdominal, musculoskeletal, cardiac, transrectal and transvaginal.

510(k) Summary 240 Parus Pie Medical

Comparison Chart for Substantial Equivalence

	PIE 1150 (Predicate to 250, cleared via K900469)	PIE 250 (Predicate to 240, cleared via K915647	PIE 240 Parus To be added with this submission
Technology	Linear/Curved/ Mechanical Annular	Annular	Annular/Curved/Linear
Modes	B, B+M, M	B, B+B. B+M, M	B, B+B, B+M, M
Frequencies	3.5 – 7.5 MHz	3.5-7.5 MHz	3.5-8 MHz
Applications	Abdominal/Fetal/ Pediatric/ Small organ/ Intraoperative	Abdominal / Small Organ/ Intraoperative/ Pediatric/ Peripheral Vascular/ Fetal	Abdominal / Small Organ / Transvaginal / Transrectal / Intraoperative / Neonatal Cephalic / Pediatric / Peripheral Vascular / Fetal/Cardiac/ Musculoskeletal
Scan Converter	Full digital	Full digital	Full digital
	44,44		



MAR - 1 2001

Food and Drug Administration 9200 Corporate Boulevard Rockville MD 20850

Pie Medical c/o Colleen Hittle Official Correspondent The Anson Group 7992 Castleway Drive INDIANAPOLIS IN 46250

Re: K003725

240 Parus Ultrasound Imaging Systems

Regulatory Class: II

21CFR 892.1560/Procode: 90 IYO 21CFR 892.1570/Procode: 90 ITX

Dated: November 27, 2000 Received: December 4, 2000

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 240 Parus Ultrasound Imaging Systems, as described in your premarket notification:

Transducer Model Numbers

401669 3.5/5.0 MHz Linear Array 410054 6.0/8.0 MHz Linear Array 402198 8.0 MHz Linear Array 401664 3.5/5.0 MHz Curved Array 401665 3.5/5.0 MHz Curved Array 401612 3.5 MHz Curved Array 401667 5.0/7.5 MHz Curved Array 401788 5.0/7.5 MHz Curved Array 402116 3.5/5.0 MHz Curved Array 402155 5.0/7.5 MHz Annular Array 402154 5.0/7.5 MHz Annular Array 402156 5.0/7.5 MHz Annular Array 402143 3.5 MHz Annular Array 402157 5.0/7.5 MHz Annular Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Page -3- Ms. Hittle

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.

Captain, USPHS

Acting Director, Division of Reproductive,

Abdominal, and Radiological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal		N	N						N			
Abdominal		N	N						N			
Intraoperative Abdominal		N	N						N			
Intraoperative Neurological												
Pediatric		N	N						N			
Small Organ (specify)		N	N						N			
Neonatal Cephalic		N	N						N			
Adult Cephalic			<u> </u>	1								
Cardiac		N	N						N			
Tranesophageal			1				<u> </u>					
Transrectal		N	N				···		N			
Transvaginal		N	N				<u>-</u>		N			
Transurethral	\vdash											
Intravascular	T											
Peripheral Vascular		N	N						N	<u> </u>		
Laparoscopic												
Musculo-skeletal Conventional		N	N						N			
Musculo-skeletal Superficial		N	N						N			
Other								4-16	Sham			

		Concurr	ence of CDF	tH, Office of	of Device Eval	uation (ODE)
(PLE	ASE DO	NOT WRITE	BELOW TH	IIS LINE-C	ONTINUE ON	ANOTHER PAGE IF NEEDED)
Applicable combined	modes: B	+B; B+M				510(k) Number <u>KUU 3 (3(3)</u>
Additional Comments	Small C	Organs (specific	ally, thyroid,	testicles, an	d breast)	and Radiological Devices 510(k) Number K003725
N= new indication: P=	= previous	sly cleared by F	DA; E= adde	d under App	endix E	(Division Sign-Off) Division of Reproductive, Abdominal, ENT.
Other	<u></u>			<u> 1</u>	Ll	Whit a Symm

Prescription Use_____

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic					, ,								
Fetal		N	N						N				
Abdominal		N	N						N				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric		N	N						N				
Small Organ (specify)													
Neonatal Cephalic		B]						
Adult Cephalic													
Cardiac													
Tranesophageal	+												
Transrectal	+												
Transvaginal													
Transurethral	+						-						
Intravascular													
Peripheral Vascular													
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial								6					
Other								1/	Samo				

Additional Comments					Division %	Secrementes, Abdor	ninal, ENT,
N= new indication: P=	previously cle	eared by FDA; I	E= added under	Appendix E	(Division S	la Syron	
Superficial Other					h		
Musculo-skeletal							i
Musculo-skeletal Conventional							
Laparoscopic							

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal												
Abdominal		N	N						N			
Intraoperative Adominal		N	N						N			
Intraoperative Neurological							**********					
Pediatric		N	N						N			
Small Organ (specify)		N	N					******	N			
Neonatal Cephalic							7.8.1					
Adult Cephalic							-					
Cardiac												
Tranesophageal												
Transrectal												
Transvaginal						·						
Transurethral												
Intravascular												
Peripheral Vascular		N	N						N			
Laparoscopic												
Musculo-skeletal Conventional	-	N	N				7	,,,,,,	N			
Musculo-skeletal Superficial		N	N						N			
Other								<u> </u>	<u> </u>			

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number <u>KUU'S</u>

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation											
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)		
Ophthalmic												
Fetal					-							
Abdominal												
Intraoperative Abdominal		N	N						N			
Intraoperative Neurological						7,000						
Pediatric		N	N						N	 		
Small Organ (specify)		N	N						N			
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Tranesophageal												
Transrectal			<u> </u>									
Transvaginal					-							
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Conventional		N	N						N			
Musculo-skeletal Superficial		N	N						N			
Other							7		· · · · · · · · · · · · · · · · · · ·			

Other		1		<u> </u>		1	/		<u> </u>
N= new indication:	P= prev	iously clear	ed by FDA	A; E= adde	d under Ap	pendix E	Shrirt.	a bezin	~
Additional Comme	nts: <u>Sma</u>	ıll Organs (specificall	y, thyroid,	testicles, an	d breast)	(Division Si	gn-Off)	
Applicable combine							and Radiolo	gical Devices	Abdominal, ENT,
(P	LEASE	DO NOT V	VRITE BI	ELOW TH	IS LINE	ONTINUE ON	510(k) Num	ber KUU''	A D
						ONTHIOL ON	ANOTHER PAGE IF	NEEDED)	

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		N	N						N				
Abdominal		N	N						N				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric		N	N						N				
Small Organ (specify)													
Neonatal Cephalic													
Adult Cephalic													
Cardiac													
Tranesophageal													
Transrectal	1		 	1									
Transvaginal													
Transurethral													
Intravascular													
Peripheral Vascular							·						
Laparoscopic													
Musculo-skeletal Conventional													
Musculo-skeletal Superficial													
Other							l	1	Marian				

Other					A	
N= new indication: I	= previously clea	ared by FDA; E=	added under A	Appendix E	Shirt a	Sysam
Additional Commen	ta.				(Division Sign-C	Off)
Additional Commen	15.					roductive, Abdominal, ENT
Applicable combined	modes: B+B; B	+M			and Radiologica	Devices
					510(k) Number	K003720
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Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation												
Clinical Application	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)			
Ophthalmic													
Fetal		N	N						N				
Abdominal		N	N					<u> </u>	N				
Intraoperative (specify)													
Intraoperative Neurological													
Pediatric		N	N					.,	N				
Small Organ (specify)													
Neonatal Cephalic			ŀ										
Adult Cephalic			- 										
Cardiac		N	N						N				
Tranesophageal	<u> </u>												
Transrectal	<u> </u>	}											
Transvaginal							-	-					
Transurethral													
Intravascular				<u> </u>									
Peripheral Vascular					<u> </u>								
Laparoscopic													
Musculo-skeletal	1												
Conventional													
Musculo-skeletal Superficial													
Other									1				

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Applicable combined modes	· DID- DIM				Division of Reproductive, Abdominal, EN
Additional Comments:					(Division Sign-Off)
N= new indication; P= previ	ously cleared by	FDA; E= a	dded under.	Appendix E	Division Sign-Off)
	!				
Other					
Superficial					
Musculo-skeletal					
Conventional		İ		İ	

Prescription Use_____

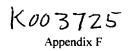
Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other									1	

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additional Comments:	(Division Sign-Off)
authoriza Comments.	Division of Reproductive, Abdominal, ENT,
pplicable combined modes: B+B; B+M	and Radiological Devices
·	510(k) Number K003725

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Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	Α	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal		N	N				,		N		
Intraoperative Abdominal		N	N						N		
Intraoperative Neurological											
Pediatric		N	N						N	 	
Small Organ (specify)		N	N						N		
Neonatal Cephalic		N	N						N		
Adult Cephalic											
Cardiac	 										
Tranesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular		N	N						N		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other								/			

= new indication: P= previously cleared by FDA; E= added under Appendix E	Sound be Syram
dditional Comments: Small Organs (specifically, thyroid, testicles, and breast)	(Division Sign-Off)
pplicable combined modes: B+B; B+M	Division of Reproductive, Abdominal, ENT, and Radiological Devices 510(k) Number 1003725
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Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric			1								
Small Organ (specify)		N	N						N		
Neonatal Cephalic											
Adult Cephalic			 								
Cardiac			. 								
Tranesophageal											
Transrectal		N	N						N		
Transvaginal		N	N					5-180 ·	N		
Transurethral											
Intravascular											
Peripheral Vascular											
Laparoscopic								<u>, , , , , , , , , , , , , , , , , , , </u>			
Musculo-skeletal			 	1							
Conventional											
Musculo-skeletal											
Superficial											
Other	$oxed{oxed}$										

Peripheral					1				
√ascular	1 1								
aparoscopic									
Musculo-skeletal Conventional									
Musculo-skeletal Superficial									
Other									
N= new indication: P=					-	Jam (1 ivision Sign-C	· Sysom		
Additional Comments: Applicable combined in			vroid, testicles	s, and breast)			oductive, Abde Devices	ominal, EN	T,
	an po vioni				510	(k) Number	K003	3725	
(PLE/							ED)		
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rescription Us	e	1	-					18	

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	₽.	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal		N	N						N		
Intraoperative (specify)							, , , , , , , , , , , , , , , , , , , ,		·		
Intraoperative Neurological											
Pediatric			 -						<u> </u>		
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Tranesophageal			-								
Transrectal											
Transvaginal		-,-,- <u>-</u>									
Transurethral		·									
Intravascular											
Peripheral Vascular		N	N						N		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other	I										

	1 1				
Musculo-skeletal					
Conventional					
Musculo-skeletal					
Superficial					1 1
Other					
Additional Comments: Combined Mode: B + M				(Division Sign-Off Division of Reproc and Radiological D 510(k) Number	ductive, Abdominal, ENT, Devices
(PLEASE D	O NOT WRITE	E BELOW THIS LI	NE-CONTINUE ON	ANOTHER PAGE IF NEEDE	D)
Conventional Musculo-skeletal Superficial Other N= new indication: P= previously cleared by FDA; E= added under Appendix E Additional Comments: Combined Mode: B + M Division Sign-Off) Division of Reproductive, Abdominal, ENT, and Radiological Devices 510(k) Number KOC3725 (PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED) Concurrence of CDRH, Office of Device Evaluation (ODE)					
Prescription Use					19



Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal	-	N	N						N		
Abdominal	-	N	N						N		
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric		N	N						N	<u> </u>	
Small Organ (specify)		N	N						N		
(specify) Neonatal Cephalic	1	N	N						N		
Adult Cephalic				1							
Cardiac											
Tranesophageal											
Transrectal	-	<u> </u>									
Transvaginal											
Transurethral	1										
Intravascular											
Peripheral Vascular									·		
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial							ļ.,				
Other						<u> </u>		. 1 6	0		

N= new indication: P= previously cleared by FDA; E= added under Appendix E	Simil de lesson
Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)	(Division Sign-Off) Division of Reproductive, Abdominal, ENT
Applicable combined modes: B+B; B+M	and Radiological Devices
	510(h) Number K003775

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Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation										
Clinical Application	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric											
Small Organ (specify) Neonatal Cephalic		N	N						N		
Neonatal Cephalic					<u>.</u> 5						
Adult Cephalic											
Cardiac											
Tranesophageal											
Transrectal			1								
Transvaginal		N	N						N		
Transurethral											
Intravascular	1									· ·	
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	-A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic						:					
Fetal											
Abdominal											
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric							1				
Small Organ (specify)		N	N						N		
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Tranesophageal	-										
Transrectal	1	N	N						N		
Transvaginal									 - 		
Transurethral				-							
Intravascular											
Peripheral Vascular	1	 									
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other							_1		le les	_l	

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(Division Sign-Off)
Division of Reproductive, Abdominal, EN
and Radiological Devices
510(k) Number <u>K003725</u>

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Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	В	М	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal	-	N	N						N		
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric		N	N						N		
Small Organ (specify)											
(specify) Neonatal Cephalic	T										
Adult Cephalic	1		1								
Cardiac	+	N	N						N		
Tranesophageal	1										
Transrectal	+-				1						
Transvaginal											
Transurethral											
Intravascular		1									
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional			1								
Musculo-skeletal Superficial											
Other											

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ther				.l				<u> </u>		
N= new indication: P=	previously c	leared by F	DA; E= add	ed under A	ppendix E	8/1	ind la	lozom		
Additional Comments:						(Divisio	on Sign-O	ff) (oductive, Abd		ENT
Applicable combined n						and Rad	liological	Devices	125	
					CONTINUE OF	510(k)	Number	KUUA	116	ر
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		Concurr	ence of CD	RH Office	e of Device Eva	luntion (ODE)				



Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation										
	A	В	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)	
Ophthalmic											
Fetal		N	N						N		
Abdominal	-			<u> </u>							
Intraoperative (specify)											
Intraoperative Neurological											
Pediatric	T										
Small Organ (specify)		N	N						N		
Neonatal Cephalic	T					Ė					
Adult Cephalic											
Cardiac											
Tranesophageal	+-	1									
Transrectal	+										
Transvaginal		N	N						N		
Transurethral											
Intravascular		 									
Peripheral Vascular	-										
Laparoscopic											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other								V	1 lans		

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT,

and Radiological Devices

510(k) Number K CO3 / HER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____